## REMARKS

Claims 1, 8-19, 27-34 and 38-56 are currently pending. Claims 2-7 are canceled without prejudice and new claims 57-63 have written support, for example in original claims 1-7. No new matter has been introduced herewith. The following addresses the substance of the Office Action.

**Written Description**

The Examiner has rejected Claims 2, 4-7 and 10-15 under 35 U.S.C. § 112, first paragraph as failing to meet the written description requirement. In particular, the Examiner stated that, to adequately describe the genus of immunogenic fragments, derivatives, or nucleic acids encoding said fraction or derivatives, the Applicant must also give a functional limitation of immunogenic fragments, derivatives, or nucleic acids encoding said fraction or derivatives.

The Applicants have canceled claims 2-7 and added new claims 57-63, in which the term "immunogenic fragment" is replaced with with "structural protein" of the *S. zooepidemicus* or the *Chlamydophila*, or an "immunogenic portion" thereof. The amendment has support on page 10 lines 15-16 and on page 17 lines 10-11. Structural proteins of *S. zooepidemicus* and *Chlamydophila* are well known in the art and specific examples are disclosed in the application, for example on page 9 line 28 to page 10 line 13 and on page 17 line 17 to page 20 line 7. Moreover, for a portion of a structural protein to be immunogenic, the skilled person would appreciate the inherent limitations imposed on such a portion. Specifically, the portion must generally be at least five amino acids in length and must be capable of raising a specific immune response against the organism from which it was - derived. Methods for detecting an immune response are routine in the art and are described in the application.

The Applicants have replaced the term "derivative" with "sequence variant," and have defined sequence variant as having at least 90% identity with the native protein or the immunogenic portion thereof. The amendment has support on page 11 lines 18-24 of the application as filed. The Applicants have also deleted refcrence to the immunogenic fragments, and the nucleic acid molecules encoding them, from Claims 12-15.

In view of the amendments to the claims and the above remarks, the Specification provides sufficient written description for the amended claims and the Applicants respectfully request removal of the rejection.

**Anticipation**

The examiner has alleged that Claims 1, 3 and 8 are anticipated under 35 U.S.C. § 102(b) by Mackenzie et al. (EP 0415794A1) and Jira et al. (US 20030039667). In response, the Applicants have amended Claim 1 to specify that the agent comprises attenuated *M cynos*, which has support in original Claim 3. Mackenzie et al. discloses a vaccine composition which comprises an antigen associated with a mycoplasma such as *M. cynos* (see Claim 2). However, Mackenzie et al. does not disclose whole cells of *M. cynos* that are attenuated. Accordingly, Claims 1, 3 and 8 are novel over Mackenzie et al.

Jira et al. discloses an anti-fungal vaccine which, optionally, may be combined with another type of vaccine, including a vaccine against mycoplasma (paragraph 0051). Specifically, Jira et al. discloses that the anti-fungal composition can be combined with a vaccine which contains an antigen associated with a mycoplasma (paragraph 0054). However, Jira et al. does not disclose whole cells of *M. cynos*, let alone attenuated whole cells of *M. cynos*. Accordingly, Claims 1, 3 and 8 are novel over Jira et al.

**Obviousness**

The Examiner has rejected all of the claims in various combinations under 35 U.S.C. § 103(a) as being obvious over Mackenzie et al. in view of Jacobs et al. (US 6,682,745), Brown et al. (US 5,661,006), Hechard et al. (J Med Microb 52:35-40), Hansen, et al. (US 5,665,363), Masubuchi et al. (J Vet Med Sci 64(12):1165-1168), Marciani et al. (US 6,080,725) and Haanes et al. (US 5,753,235). The Applicants disagree for the following reasons.

As discussed above, Mackenzie et al. does not disclose a vaccine composition for vaccinating dogs comprising an agent capable of raising an immune response against *Mycoplasma cynos* (*M. cynos*) in a dog, wherein said agent comprises attenuated *M. cynos*. Moreover, none of the cited references provide a reason to one of skill in the art to develop such a vaccine that elicits an immune response that is protective against Canine Infectious Respiratory Disease (CIRD).

**Section 9**

In Section 9 of the office action, the Examiner has alleged that Claims 1-3, 8-11, 40 and 42 are obvious over Mackenzie et al. in view of Jacobs et al. (US 6,682,745) and Brown et al. (US 5,661,006). Mackenzie et al. does not disclose that a vaccine composition comprising *M*

*cynos* can or should be used to combat respiratory disease in dogs. Indeed, Mackenzie et al. does not disclose any reason for making a vaccine against *M. cynos*.

Jacobs et al. discloses using live attenuated bacteria for manufacturing vaccines and lists various examples of pathogenic bacteria that may be used. Contrary to the Examiner's assertion, Jacobs et al. does not disclose a vaccine composition comprising *Streptococcus zooepidemicus* (*S. zooepidemicus*) for dogs. Rather, *S. zooepidemicus* is listed as a horse pathogen (column 3, lines 17-45), not a dog pathogen (see column 4, lines 30-37). Accordingly, it is not prima facie obvious to combine a vaccine to the well known horse pathogen *S. zooepidemicus* with a vaccine to *M. cynos* in a single composition. Only the present application correlates *M. cynos* with canine respiratory disease and therefore provides a reason for preparing *M. cynos* into a vaccine. Only the present application additionally correlates *S. zooepidemicus* with canine respiratory disease and therefore provides reason for combining the *M. cynos* vaccine with a vaccine for *S. zooepidemicus*.

Brown et al. discloses a vaccine composition comprising a canine coronavirus (CCV) spike protein that can be used to immunize dogs against CCV Infection. The CCV strains disclosed in Brown et al. are Group 1 canine coronavirus strains which are completely distinct viruses from the canine respiratory coronavirus (CRCV) which is referred to in the present application. Referring to page 24 of the present application as filed, CRCV is the virus disclosed in WO 2004/011651. The CCV spike protein disclosed in Brown et al. is highly unrelated to the CRCV spike protein disclosed in WO 2004/011651. For example, CCV-6 has 18% amino acid identity with CRCV, Insavc-1 has 18.6% amino acid identity with CRCV, and 1-71 has 19.2% amino acid identity with CRCV. Brown et al. does not disclose that CCV causes respiratory disease in dogs. Appended herewith is a copy of Tennant et al. 1991 Res in Vet Sci 51:11-18, which shows that, although CCV was isolated from respiratory tissue of dogs following experimental infection, no clinical respiratory signs were detected. Since the two viruses are so unrelated, Brown et al. is not relevant to establishing prima facie obviousness.

**Section 10**

In Section 10 of the office action, the Examiner has alleged that Claims 1, 3-4 and 8 are obvious over Mackenzie et al. in view of Hechard et al (2003).

As discussed above, Mackenzie et al. does not disclose that a vaccine composition comprising *M. cynos* can or should be used in dogs; Mackenzie at al does not disclose that a vaccine composition comprising *M. cynos* can or should be used to treat respiratory disease in dogs; Mackenzie et al does not disclose any reason for making a vaccine against *M. cynos*.

Hechard et al. evaluates the protective effect of DNA immunization with the gene encoding the major outer-membrane protein of *Chlamydophila abortus* (*C. abortus*). *C. abortus* is described as a common cause of abortion in sheep and goats and also as a zoonotic risk to pregnant women. Hechard et al. does not disclose that the *C. abortus* vaccine would or could be used in dogs. In addition, Hechard et al. only discloses the use of *C. abortus* in a vaccine composition to protect against abortion induced by *C. abortus*. Hechard et al. does not suggest that a vaccine against *C. abortus* would or could be used to combat respiratory disease. Thus, the skilled artisan would have no reason to combine a *C. abortus* vaccine with a *M. cynos* vaccine. It is only the teachings of the present application which demonstrate the association of both *Chlamydophila* and *M. cynos* with canine respiratory disease, and thus provide the skilled person with a reason to combine them in a single vaccine.

**Section 11**

In Section 11 of the office action, the Examiner has alleged that Claims 1, 3-5, 8-9, 12-13 and 41 are obvious over Mackenzie et al. in view of Hansen at al. (US 5,665,363).

As discussed above, Mackenzie et al. does not disclose that a vaccine composition comprising *M. cynos* can or should be used in dogs; Mackenzie et al does not disclose that a vaccine composition comprising *M. cynos* can or should be used to treat respiratory disease in dogs; Mackenzie et al does not disclose any reason for making a vaccine against *M. cynos*.

Hansen et al discloses a method of vaccinating an animal with dried pellets of biologically active material, and specifies that the material may be *Bordetella bronchiseptica*, canine adenovirus, canine parainfluenza or *Chlamydia psittaci*. Although Hansen et al. states that this method can be used to vaccinate animals, including dogs, it does not disclose that a vaccine against any of these specific agents can be used for vaccinating dogs. In addition, Hansen et al. does not disclose that *B. bronchiseptica*, canine adenovirus, canine parainfluenza or *C. psittaci* are involved in canine respiratory disease. Moreover, the adjuvant system disclosed in Mackenzie et al. does not appear to be compatible with the vaccination method disclosed in

Hansen et al. Accordingly, the skilled artisan would not combine the disclosure of these two documents. Thus, the skilled person would have no reason to combine a *B. bronchisetica*, canine adenovirus, canine parainfluenza or *C. psittaci* vaccine with a *M. cynos* vaccine.

**Section 12**

In Section 12 of the Office Action, the Examiner alleged that Claims 1, 3, 6 and 8 are obvious over Mackenzie et al. in view of Masubuchi et al. (2002). As discussed above, Mackenzie et al. does not disclose that a vaccine composition comprising *M. cynos* can or should be used in dogs; Mackenzie et al. does not disclose that a vaccine composition comprising *M. cynos* can or should be used to treat respiratory disease in dogs; Mackenzie et al. does not disclose any reason for making a vaccine against *M. cynos*.

Masubuchi et al. discusses experimental infection of cats with *Chlamydophila Felis* (*C. felis*) and states that *C. felis* is primarily considered to be an ocular pathogen in cats. Pathological examination demonstrated the disease caused was limited to-conjunctivitis with no pathological changes identified in the lung. Thus, from Masubuchi et al. the skilled person would recognize the value of inactivated or attenuated *C. felis* in a vaccine composition only to protect against ocular disorders. Masubuchi et al. does not disclose that the *C. felis* vaccine would or could be used in dogs. *Masubuchi et al.* does not suggest that a vaccine against *C. felis* would or could be used to combat respiratory disease in dogs. Thus, the skilled person would have no reason to combine a *C. felis* vaccine with a *M. cynos* vaccine. It is only the teachings of the present application that demonstrate the association of both *Chlamydophila* and *M. cynos* with canine respiratory disease, and thus give reason for the skilled person to combine them in a single vaccine.

**Section 13**

In Section 13 of the office action, the Examiner alleged that Claims 1, 3, 6 and 8 are obvious over Mackenzie et al in view of Marciani et al. (US 6,080,725).

As discussed above, Mackenzie et al. does not disclose that a vaccine composition comprising *M. cynos* can or should be used in dogs; Mackenzie et al does not disclose that a vaccine composition comprising *M. cynos* can or should be used to treat respiratory disease in dogs; Mackenzie et al does not disclose any reason for making a vaccine against *M. cynos*.

Marciani et al. discloses an adjuvant system comprising saponin-lipophile conjugates for use in vaccine compositions. The vaccine compositions may comprise antigens from *Chlamydia pneumoniae* or *Chlamydia trachomatis*. Although Marciani et al. states that this adjuvant system can be used for vaccinating animals, including dogs, it does not disclose that a vaccine against *C. pneumoniae* or *C. trachomatis* can be used for vaccinating dogs. In addition, Marciani et al. does not disclose that *C. pneumoniae* or *C. trachomatis* are involved in canine respiratory disease.

Thus, it cannot be prima facie obvious from Mackenzie et al. and Marciani et al. to combine a *M. cynos* vaccine with a *C. pneumoniae* or *C. trachomatis* as claimed.

**Section 14**

In Section 14 of the Office Action, the Examiner alleged that Claims 1, 3 and 14 are obvious over Mackenzie et al. in view of Haanes e al. (US 5,753,235). As discussed above, Mackenzie et al. does not disclose that a vaccine composition comprising *M. cynos* can or should be used in dogs; Mackenzie et al. does not disclose that a vaccine composition comprising *M. cynos* can or should be used to treat respiratory disease in dogs; Mackenzie et al. does not disclose any reason for making a vaccine against *M. cynos*.

Haanes et al. discloses the use of recombinant canine herpes virus (CHV) in a vaccine to protect animals from CHV infection, and mentions its combination with compounds derived from a variety of infectious agents to form a single therapeutic composition (see column 14, line 23 to column 15, line 35). Haanes et al. does not disclose that the CHV vaccine would or could be used to combat respiratory disease in dogs. Thus, the skilled person would have no reason to combine a CHV vaccine with a *M. cynos* vaccine.

In view of the amendments to the claims and the above remarks, the Applicants respectfully request removal of the rejections under 35 U.S.C. § 103(a).

*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present

disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

*Co-Pending Applications of Assignee*

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

| Serial Number | Title | Filed |
|---|---|---|
| 11/849,931 | VACCINE COMPOSITION FOR VACCINATING DOGS AGAINST CANINE INFECTIOUS RESPIRATORY DISEASE | September 4, 2007 |
| 10/566,866 | ANTIGEN DELIVERY SYSTEM | February 2, 2006 |
| 10/522,513 | CANINE RESPIRATORY CORONAVIRUS (CRCV) SPIKE PROTEIN, POLYMERASE AND HEMAGGLUTININ/ESTERASE | June 22, 2006 |

## CONCLUSION

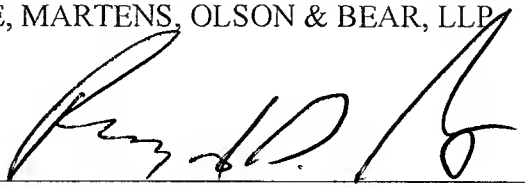
In view of Applicants' amendments to the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 17 June 2008

By: 

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